

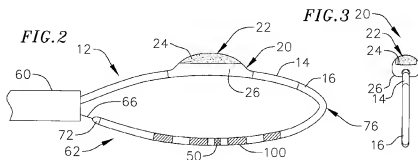
REMARKS

I. PRELIMINARY REMARKS

No claims have been added or canceled. Claims 14, 17, 21, 22, 25 and 26 have been amended. Claims 14-17, 21-30, 37-39, 45 and 46 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

II. BRIEF DESCRIPTION OF AN EXEMPLARY EMBODIMENT

The present inventions, as defined by the claims, are directed to probes that may be used for therapeutic purposes. Referring to Figures 2 and 3, one exemplary probe includes a catheter 12 that is carried within a sheath 60. The catheter 12, which may be bent into a loop 62 using a pull wire 66 (Figure 2) or by connecting the catheter to distal end of the sheath 60 (Figure 14), includes a hinge 74 (Figure 13). The hinge is located within the portion of the catheter 12 that forms the apex 76 of the loop 62. An inflatable electrode 20 is supported on the catheter 12.



III. REJECTION UNDER SECTION 112

Claims 14 and 17 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection under 35 U.S.C. § 112, second

paragraph, is respectfully traversed to the extent that it is applicable to the claims as amended above. Reconsideration thereof is respectfully requested.

Claim 14 calls for "an outer member defining a distal end ..." and "an elongate body ... defining a distal region and a distal end." As such, there is antecedent basis for both "distal ends." Claim 14, prior to the amendment above, also indicated that "the distal region of the elongate body [includes] a hinge portion located proximal of the distal end." To the extent that this was the source of the Examiner's confusion, applicant respectfully submits that one of skill in the art who had reviewed the present application would have understood that the "distal end" being referred to here was the "distal end" of the subject of this phrase, i.e. the distal end of the "elongate body." Nevertheless, in order to obviate the issue, claim 14 has been amended so as to specifically recite that "the distal region of the elongate body [includes] a hinge portion located proximal of the distal end **of the elongate body.**"

The rejection of claim 17 has been obviated by the amendment above.

In view of the foregoing, applicant respectfully submits that the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

IV. PRIOR ART REJECTIONS

A. The Rejections

Claims 14, 15 and 38 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,076,012 to Swanson ("the Swanson '012 patent"). Claim 16 has been rejected under 35 U.S.C. § 103 as being unpatentable over the Swanson '012 patent. Claims 14-17, 38 and 39 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Swanson '012 patent and U.S. Patent No. 5,715,825 to Crowley ("the Crowley '825 patent"). Claim 46 has been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Swanson '012 patent, the Crowley '825 patent, and U.S. Patent No. 6,152,920 to Thompson ("the Thompson '920 patent"). Claims 21-30 and 45 have been rejected under 35 U.S.C. § 103

as being unpatentable over the combined teachings of the Swanson '012 patent and the Thompson '920 patent. The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed to the extent that they are applicable to the claims as amended above. Reconsideration thereof is respectfully requested.

B. Discussion Concerning the Section 102 Rejection of Claims 14, 15 and 38 Based Solely on the Swanson '012 Patent

At the outset, applicant notes that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131, citations omitted. MPEP § 2131 also indicates that "***[t]he elements [of the prior art reference] must be arranged as required by the claim.***" [Emphasis added.] Accordingly, "picking, choosing and combining various disclosures that are not directly related to one another by the teachings of the cited reference" has no place in the making of an anticipation rejection. *In re Arkley, Eardley, and Long*, 172 USPQ 524, 526 (CCPA 1972).

Independent claim 14 calls for a combination of elements comprising "an outer member," "an elongate body carried within the outer member interior bore and defining a proximal region, a distal region and a distal end operably connected to the distal end of the outer member, the elongate body including an internal fluid lumen extending from the proximal region to the distal region, and the distal region of the elongate body including a hinge portion located proximal of the distal end of the elongate body" and "an inflatable tissue coagulation body supported ***on the elongate body distal region.***" The respective combinations defined by claims 15 and 38 include, *inter alia*, the elements recited in claim 14.

The Swanson '012 patent does not disclose this combination of elements in the arrangement defined by independent claim 14. Even assuming for the sake of argument that the Swanson '012 patent discloses some of the claimed elements in Figure 82 and discloses the remaining claimed elements in Figures 33-36, as asserted on page 4 of the Office Action, the Swanson '012 patent does not disclose these elements ***arranged***

as required by the claim. Instead, the elements at issue are presented in two different devices and the Office Action failed to point to any aspect of the Swanson '012 patent which indicated that these elements **should be** mixed and matched in the manner presented in the Office Action.

The rejection of claims 14, 15 and 38 under 35 U.S.C. § 102 should, therefore, be withdrawn.

C. Discussion Concerning the Section 103 Rejection of Claim 16 Based Solely on the Swanson '012 Patent

Faced with the failure of the cited reference to disclose a “sensing element” and the “inflatable tissue coagulation body” on **different sides** (i.e. one proximal side and the other distal) of the “hinge portion,” the Office Action simply asserted that it would have been obvious to move the Swanson temperature sensing elements 540 (Figure 3A) off the electrode elements 28 and/or inflatable structures illustrated in Figures 82-84 and, apparently, onto an electrode-less portion of the spline element 172 on the other side of the purported “hinge portion” because “rearranging parts of an invention involves only routine skill in the art” and cited *In re Japinske*, 86 USPQ 70 (CCPA 1950) in support. [Office Action at page 5.] Although the Examiner did not specify which portion of the *Japinske* decision supports the assertion in the Office Action, the portion that at least appears to be applicable reads as follows:

In the brief of the Solicitor for the Patent Office it is pointed out that the claim reads on Cannon except as to the final limitation reading “means disposed in alignment with said opening for contact by said depending means to start the pressing operation of said hydraulic press.” As to that limitation it was held that there would be no invention in shifting the starting switch disclosed by Cannon to a different position **since the operation of the device would not thereby be modified.**

We find no error in the holding as to claim 3.

86 USPQ at 73, *emphasis added*. Contrary to the situation in *Japinske*, the modification proposed in the outstanding Office Action would clearly change the operation of the Swanson device. The purpose of the Swanson temperature sensing elements 540 is to sense temperature at the electrode elements 28 in order to control the energy supplied

to the electrode elements. [Column 37, lines 44-49.] Moving the temperature sensing elements 540 away from the electrode elements 28 would clearly change “the operation of the device” and, accordingly, the *Japinske* decision does not support a conclusion of obviousness.

In view of the foregoing, applicant respectfully submits that the Office Action failed to establish a *prima facie* case of obviousness and that the rejection of claim 16 under 35 U.S.C. § 103 should be withdrawn.

D. Discussion Concerning the Section 103 Rejection of Claims 14-16 and 38 Based on the Swanson '012 and Crowley '825 Patents

Independent claim 14 calls for a combination of elements comprising “an outer member,” “an elongate body carried within the outer member interior bore and defining a proximal region, a distal region and a distal end operably connected to the distal end of the outer member, **the elongate body including an internal fluid lumen** extending from the proximal region to the distal region, and the distal region of the elongate body including a hinge portion located proximal of the distal end of the elongate body” and “an inflatable tissue coagulation body supported **on the elongate body distal region.**” The respective combinations defined by claims 15,16 and 38 include, *inter alia*, the elements recited in claim 14.

The Office Action has apparently taken the following positions: (1) the Swanson spline element 172, wire 184 and cap 186 (Figures 25-29) together correspond to the claimed “elongate body ... including a hinge portion,” and (2) it would have been obvious to mount one of the inflatable structures illustrated in Figures 82-84 on the spline element 172.

With respect to the first position, the purported “elongate body,” i.e. spline element 172, wire 184 and cap 186, do not include an internal fluid lumen and there is nothing in either of the Swanson '012 and Crowley '825 patents that would even remotely suggest placing an internal fluid lumen within a wire. To that end, it should be noted that the Swanson '012 patent describe splines as being “a thin, rectilinear strip of resilient metal,

plastic material, or composite." [Column 17, lines 1-7.] For this reason alone, the rejection under 35 U.S.C. § 103 should be withdrawn.

Turning to the second position, nothing in the Swanson '012 and Crowley '825 patents suggest moving the one of inflatable structures illustrated in Figures 82-84 onto the spline element 172. That issue notwithstanding, the inflatable structures illustrated in Figures 82-84 are carried on the distal end of a catheter tube that (although not shown) would include a lumen to deliver fluid to the inflatable structures. The Office Action did not even attempt to explain how this could be accomplished on a spline, let alone a spline that is movable relative to the underlying catheter in the manner illustrated in the Swanson patent.

As the cited references fail to teach or suggest the combination of elements recited in independent claim 14, applicant respectfully submits that the rejection of claims 14-16 and 38 under 35 U.S.C. § 103 should be withdrawn.

E. Discussion Concerning the Section 103 Rejection of Claim 45 Based on the Swanson '012 and Thompson '920 Patents

The Thompson '920 patent, which has been cited for its pivot assembly teachings, fails to remedy the deficiencies in the Swanson '012 patent discussed in Section IV-C above. As such, claim 45 is patentable for at least the same reasons as independent claim 14 and the rejection of claim 45 under 35 U.S.C. § 103 should be withdrawn.

F. Discussion Concerning the Section 103 Rejection of Claims 17 and 39 Based on the Swanson '012 and Crowley '825 Patents

Claim 17 has been amended so as to depend from independent claim 14. Applicant respectfully submits that claims 17 and 39 are patentable for the reasons presented in Section IV-D above and that the rejection of claims 17 and 39 under 35 U.S.C. § 103 should be withdrawn.

G. Discussion Concerning the Section 103 Rejection of Claim 46 Based on the Swanson '012, Crowley '825 and Thompson '920 Patents

Claim 46 now indirectly depends from independent claim 14 by virtue of the amendment to claim 17.

The Thompson '920 patent, which has been cited for its pivot assembly teachings, fails to remedy the deficiencies in the Swanson '012 and Crowley '825 patents discussed in Section IV-D above. As such, claim 46 is patentable for at least the same reasons as independent claim 14 and the rejection of claim 46 under 35 U.S.C. § 103 should be withdrawn.

H. Discussion Concerning Claims 21-30

Independent claim 21 calls for a combination of elements including, *inter alia*, “an elongate catheter tube, defining a distal region that supports the tissue coagulation body and a distal end, adapted to be carried within the outer member interior bore and extend outwardly from the interior bore such that the distal region forms a loop, ***the elongate catheter tube including a hinge located proximal of the distal end*** and defining the apex of the loop formed by the distal region, the hinge having a flexibility that is greater in a bending direction than the flexibility of the portions of the elongate catheter tube.” The combinations defined by claims 22-30 include, *inter alia*, the elements recited in claim 21. The cited references fail to teach or suggest the claimed combinations.

For example, and referring to Figures 25-27 of the Swanson '012 patent, the Office Action has apparently interpreted the claims in such a manner that the Swanson wire 184 corresponds to the claimed “elongate body” and the cap 186 on the end of the wire, which includes a passage 188¹ for the spline element 172, corresponds to the claimed “hinge portion.” [Office Action at page 8.] The Thompson '920 patent includes a pivot assembly 120 (Figure 15) that is mounted on the end of a sheath 114 and is

¹ The locations of reference numerals 186 and 188 appear to have been inadvertently reversed in Figure 26.

connected to the distal end of a probe by a connector 132. The Office Action has apparently taken the position that it would have been obvious to somehow add the pivot assembly 120 disclosed in the Thompson '920 patent to the device illustrated in Figures 25-27 of the Swanson '012 patent. [Office Action at page 10.] The Office Action did not, however, even attempt to provide any indication as to how this modification of the Swanson spline-based device would occur, what the resulting structure would be, and what would have motivated one of skill in the art to make this modification.² That issue notwithstanding, applicant respectfully submits that the result would not be an "elongate catheter tube including a hinge located proximal of the distal end" of the catheter tube.

Accordingly, the Office Action failed to establish a *prima facie* case of obviousness and the rejection of claims 21-30 under 35 U.S.C. § 103 should be withdrawn.

V. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

² It should also be noted that, to the extent that the Examiner may find it applicable to the present application, the Swanson '012 patent discloses how such a pivot assembly would combined with a catheter. The pivot assembly is secured to the distal end of the sheath and to the ***distal end of the catheter***. [Note Figures 77A-78C.]

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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Date

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